DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 12, 2015

BenQ Materials Corporation
Ms. Kenix Chang
Regulatory Affairs Specialist
29, Jianguo E. Road
Gueishan 33341,
Taoyuan, Taiwan (R.O.C)

Re: K143462
Trade/Device Name: AnsCare ChitoClot Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 4, 2015
Received: February 9, 2015

Dear Ms. Chang:

This letter corrects our substantially equivalent letter of May 8, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143462

Device Name
AnsCare ChitoClot Gauze

Indications for Use *(Describe)*
AnsCare ChitoClot Gauze (prescription use):
For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions, lacerations.

AnsCare ChitoClot Gauze (over-the-counter use):
To control bleeding of lacerations, minor cuts and abrasions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5

510(k) Summary

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: 25th November, 2014

5.3 Submitter: BenQ Materials Corporation

Address:	29, Jianguo E. Rd., Gueishan 33341, Taoyuan, Taiwan (R.O.C)
Phone:	+886-3-3748800
Fax:	+886-3-3763030
Contact:	Kenix Chang, Regulatory Affairs Specialist (Kenix.Chang@BenQMaterials.com)

5.4 Identification of the Device:

Proprietary/Trade name:	AnsCare ChitoClot Gauze
Classification Name:	Dressing, Wound, Drug
Device Classification:	Unclassified
Regulation Number:	—
Panel:	General & Plastic Surgery
Product Code:	FRO

5.5 Identification of the Predicate Device:

Predicate Device Name:	Chito-SAM™ Gauze
Manufacturer:	SAM Medical Products
Product Code:	FRO
510(k) Number:	K133121
Predicate Device Name:	CELOX Gauze PRO
Manufacturer:	MedTrade Products Ltd.
Product Code:	FRO

510(k) Number:	K113560
Predicate Device Name:	CELOX Hemostatic Granules on Sheet
Manufacturer:	MedTrade Products Ltd.
Product Code:	FRO
510(k) Number:	K080097

5.6 Intended Use and Indications for Use of the subject device.

AnsCare ChitoClot Gauze (prescription use):
For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions, lacerations.

AnsCare ChitoClot Gauze (over-the-counter use):
To control bleeding of lacerations, minor cuts and abrasions.

5.7 Device Description

The AnsCare ChitoClot Gauze is made of a non-woven fabric derived from chitosan fibers. The device is made of 100% chitosan – it is not coated or impregnated with chitosan granules. Chitosan is a naturally occurring polysaccharide usually derived from shellfish, and its hemostatic properties are widely recognized in the biomedical field. When applied directly on a wound with firm pressure, the AnsCare ChitoClot Gauze will turn into a gel-like condition to absorb the blood and seal the wound. The AnsCare ChitoClot Gauze also contains acetic acid as an acidity regulator and Polysorbate 20 as a surfactant.

5.8 Non-clinical Testing

A series of non-clinical studies were conducted on the proposed device. All the test results demonstrate that AnsCare ChitoClot meet the requirements of its pre-defined acceptance criteria and intended uses.

Biocompatibility testing:

- Cytotoxicity Test
- Skin Irritation Test
- Skin Sensitization Test (Closed-patch Method)
- Acute Systemic Toxicity (intraperitoneal and intravenous)
- Hemolysis Test Report
- Pyrogen, Protein content and Residual solvent Testing Report

Bench performance testing included functional testing for:

- Absorb Test
- pH
- Tensile Strength (wet and dry)
- Platelet Aggregation
- Extreme Environmental Conditions Test
- Competitor analysis

Animal Testing:

- *In-vivo* Hemostasis Test

5.9 Substantial Equivalence Determination

The AnsCare ChitoClot Gauze submitted in this 510(k) file is substantially equivalent in intended use, main materials, design, safety and performance claims to the cleared Chito-SAM™ Gauze (K133121), CELOX Gauze PRO (K113560) and CELOX Hemostatic Granules on Sheet (K080097). Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Substantial Equivalence Comparison：

	Proposed device	Predicate device	Predicate device	Predicate device
Item	AnsCare ChitoClot Gauze	Chito-SAM™ Gauze	CELOX Gauze PRO	MedTrade CELOX Hnemostatc Granules on Sheet
K number	—	K133121	K113560	K080097
Regulation Number	—	—	—	—
Classification	Unclassified	Unclassified	Unclassified	Unclassified
Product Code	FRO	FRO	FRO	FRO
Indications for Use (prescription use)	For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions, lacerations.	For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions and lacerations.	Under the supervision of a healthcare professional CELOX Gauze PRO / CELOX PRO Hemostatic Gauze / OMNI-STAT Gauze / OMNI-STAT Hemostatic Gauze for minor external bleeding from wounds and procedures (Rx) is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate	MedTrade Products CELOX Hemostatic Granules on Sheet is indicated for temporary external use to control moderate to severe bleeding,

			from sutures and/or surgical procedures. Under the supervision of a healthcare professional CELOX Gauze PRO / CELOX PRO Hemostatic Gauze / OMNI-STAT Gauze / OMNI-STAT Hemostatic Gauze for moderate to severe external bleeding wounds (Rx) is indicated for temporary external treatment for controlling moderate to severe bleeding.	
Indications for Use (OTC)	To control bleeding of lacerations, minor cuts and abrasions.	To control bleeding of lacerations, minor cuts and abrasions.	CELOX Gauze PRO (OTC) is indicated for use as a temporary topical dressing for minor cuts, minor abrasions, minor lacerations and minor burns.	Medtrade Products CELOX Hemostatic Granules on Sheet is indicated for temporary external use to control bleeding of lacerations, minor cuts, and abrasions.
Anatomical Site	External wounds	External wounds	External wounds	External wounds

Physical Composition	Soft absorbent, non-woven gauze	Soft absorbent, non-woven gauze	Non-woven gauze	High density gauze
Granules or Sheet	A non-woven fabric derived from chitosan fibers	A non-woven fabric derived from chitosan fibers	Chitosan granules adhered onto a base fabric (non-woven gauze) using a hot melt adhesive.	Chitosan granules are mechanically heat bonded on to a viscose sheet.
Material	Chitosan (Poly N-acetyl- glucosamine)	Chitosan (Poly N-acetyl- glucosamine)	Chitosan, polymer, Poly N-acetyl-glucosamine	Chitosan, polymer, Poly N-acetyl-glucosamine
Sterility	Gamma-Sterilized	Gamma-Sterilized	Gamma-Sterilized	—
Packaging	Foil Pouch	Foil Pouch	3 layer (Polyester, Aluminum and LDPE) Pouch	—
Specification	Thickness: 1.0 ± 0.2 mm Size: 3" x 6' (7.6 cm x 183 cm) (Roll) 2" x 16" (5.1 cm x 41 cm) (8 ply) 4" x 32" (10 cm x 81 cm) (8 ply) 3" x 4' (7.6 cm x 122 cm) (Roll)	Fiber Diameter: 13.4 μm Thickness: 1.0 ± 0.2 mm Size: 10 cm x 10 cm, 7.6 cm x 183 cm(Z-fold), 7.6 cm x 305 cm(Z-fold)	Various sizes ranging from 1" x 1" to 3" x 10 ft	5 foot z-folded, 5 foot z-folded, 10 foot Roll

	4" x 16" (10 cm x 41 cm) (4 ply) 4" x 4" (10 cm x 10 cm) (single-ply) 3" x 6' (7.6 cm x 183 cm) (Z-fold) 3" x 10' (7.6 cm x 305 cm) (Z-fold)			

5.10 Similarity and differences

The main predicate of this application is Chito-SAM™ Gauze produced by SAM Medical Products (K133121). The AnsCare ChitoClot Gauze is substantially equivalent in intended use, main materials, design, safety and performance claims to Chito-SAM™ Gauze (K133121). The only difference between the proposed device and predicate device is the specification. There are multiple specifications for proposed device. The predicate devices of Chito-SAM™ Gauze (K133121), CELOX Gauze PRO (K113560) and CELOX Hemostatic Granules on Sheet (K080097), also used to demonstrate the substantial equivalence with AnsCare ChitoClot Gauze in this submission. The difference of proposed device and predicate devices did not raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate devices in intended use, main materials, design, safety and performance claims.

5.11 Conclusion

After analyzing bench tests and safety testing data, it can be concluded that AnsCare ChitoClot Gauze is substantially equivalent to the predicate devices.